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Augmenting home exercise programmes in primary care physiotherapy: a pilot randomised controlled trial of the 'Exercise Buddy' model

Abstract:

Background: Non-ambulatory people with MS (PwMS) comprise 25% of the MS population. Literature reviews show insufficient evidence exists regarding physiotherapy for this population. A qualitative study suggested benefits from 'exercise buddies' who were paid carers delivering a physiotherapy home exercise programme.

Aims: To explore the feasibility and effects of 'exercise buddies' for non-ambulatory PwMS

Methods: 29 non-ambulatory PwMS (age range 43-72) were randomised to 10 weeks of 'usual care' (UC) or 'exercise buddy' (EB). PwMS were assessed with the Multiple Sclerosis Impact Scale 29 (MSIS) and the Guys Neurological Disability Scale (GNDS) pre and post intervention. Their informal caregivers (12 male, 16 female, aged 21-68) completed the Adult Carer Quality of Life (AC-QoL) questionnaire.

Findings: Using ANCOVA to adjust for pre-intervention scores there was no significant differences between groups after treatment on the MSIS-29 physical ($p=0.395$), MSIS-29 psychological ($p=0.176$) or GNDS ($p=0.177$). The ACQOL was also not significantly different between groups post treatment ($p=0.432$). Using paired t-tests the EB group improved significantly from baseline on the two components of the MSIS-29 ($p=0.024$, $p=0.009$), not seen in the UC group.

Conclusions: This pilot study found no significant between group differences post treatment. However, good feasibility and significant positive changes from baseline for the EB group warrant further exploratory work in addition to a cost analysis.

Key words: Multiple Sclerosis, exercise buddy, Physical Therapy Specialty, non-ambulatory, severe disability

Introduction:

Multiple Sclerosis (MS) is a chronic, progressive condition of the central nervous system and the leading cause of disability in young adults. Globally the median prevalence rate is estimated to be 30 per 100,000 (Dua et al., 2008). For people with MS (PwMS), progression to being non-ambulatory occurs on average 30 years after diagnosis (Confavreux et al., 2003), and it is estimated that 25% of PwMS are non-ambulatory (Coote et al., 2010, Einarsson et al., 2003). In addition, in 2006 a European survey found that the total mean annual cost was €18,000 for people with mild disability (Expanded Disability Severity Scale (EDSS) <4.0) versus up to €62,000 euro for those with severe disability levels (EDSS >7) (Kobelt et al., 2006).

Despite compiling roughly one quarter of the MS population and the higher cost associated with increasing disability, most of the literature published to date on physical therapy interventions focuses on people with mild to moderate MS (EDSS≤6.5) who are defined as being able to walk with few studies focusing on those with higher disability levels (Dalgas et al., 2008, Campbell et al., 2015, Toomey and Coote, 2012). Studies that do exist for this population suggest positive benefits for physiotherapy, but are often of low quality and infrequently use blinding, control groups or standardised outcome measures (Campbell et al., 2015, Toomey and Coote, 2012). In addition, a review of current practice in Ireland suggests that non-ambulatory PwMS receive a limited amount of physiotherapy, averaging of 3.55 hours over a three month timeframe, and is predominantly received in respite, long term care or home settings (Coote et al., 2010). Moreover, although an important aspect of comprehensive treatment for PwMS, studies within this population rarely consider how interventions impact on the carers of these people (Toomey and Coote, 2012).

The lack of available evidence, the high costs of care and the significant need of both the person and their caregiver, all highlight the need to design and evaluate interventions for this population within pragmatic primary care settings where treatment is most commonly delivered.

The Medical Research Council (MRC) provides guidance on designing complex interventions, which are defined as those that contain several interacting components such as the degree of flexibility or tailoring of the intervention (Craig et al., 2008). Using this framework we began with a review of the relevant literature (Toomey and Coote, 2012), followed by a preliminary survey amongst primary care physiotherapists in four Health Service Executive (HSE) locations to define the frequency of usual care in these areas (unpublished survey). This found that the average number of visits received by PwMS was one visit in 10 weeks. Subsequently we worked with the PwMS and their informal caregivers through consultation with MS Ireland to explore models of care that would augment the currently suboptimal amount of physiotherapy for this population. One proposed model was the use of ‘exercise buddies’, or paid professional carers, to enhance the frequency of primary care physiotherapy interventions in the home setting. This was driven by informal caregivers’ anecdotal reports that it was difficult for them to deliver the home exercise programmes (HEPs) suggested by the physiotherapists due to all of the other demands of caring. It is also well recognised that treating PwMS in their own home environment has a number of psychological and cost advantages for the participant (Chataway et al., 2006). In addition, exercise programmes carried out by PwMS have been previously found to be effective in a home setting, with benefits for physical, functional and psychological aspects (Aydin et al., 2014).

The model was informally trialled in a number of areas, using an ‘exercise buddy’ to implement the HEP designed by a primary care physiotherapist on a weekly basis. The next

step of the development process was a qualitative study of the key stakeholders (Toomey and Coote, 2013), which found substantial positive physical and psychological benefits for both the person and their caregiver. The aim of this pilot study was to investigate the feasibility (e.g. acceptability, practicality and implementation of intervention procedures and measures) and to explore the effects of an ‘exercise buddy’ to augment a physiotherapist-prescribed HEP in comparison to a physiotherapist-prescribed HEP within usual primary care physiotherapy conditions for non-ambulatory PwMS.

Methods:

This pilot study was a single-blind randomised controlled pragmatic design with PwMS randomised to receive 10 weeks of either ‘usual care’ or the ‘exercise buddy’ intervention within a primary care physiotherapy setting. A duration of 10 weeks was chosen based on informal consultation with the primary care physiotherapists and the previously described qualitative development work conducted with the PwMS and their caregivers and MS Ireland (Toomey and Coote, 2013) to ascertain a duration that would be acceptable and feasible to all stakeholders for testing in the pilot study. Ethical approval was granted by the Health Service Executive (HSE) Mid-West and West Research Ethics Committees. All participants including exercise buddies, physiotherapists, PwMS and their respective caregivers provided written informed consent.

Participants and randomisation

A convenience sample of non-ambulatory PwMS was invited to take part through contact with MS Ireland and four local primary care physiotherapy teams. The caregivers of included participants and their designated primary care physiotherapist (based on existing primary care allocations) were also invited to take part in the study. Inclusion criteria for PwMS were a

definite diagnosis of MS and that they were non-ambulatory (i.e. an inability to take more than a few steps with assistance for transfer purposes). Potential participants were excluded if they were experiencing an acute exacerbation of symptoms, had any other unstable medical problems or were under 18 years of age. Screening was conducted by a study researcher (ET) who also determined sufficient cognitive status for participation as defined by their ability to communicate their understanding of what the study involved and that their participation was voluntary.

Randomisation of the PwMS (and their corresponding informal caregiver and physiotherapist) was carried out prior to baseline assessment by the second author (SC). Four opaque envelopes containing slips of paper labelled 'usual care' or 'exercise buddy' placed in a box and were randomly selected until, for each participant recruited, all pieces had been drawn. All slips were then replaced and the next group of four were removed to create an allocation sequence which was concealed from the study researcher (ET) until the end of the trial. This method was chosen to ensure similar numbers in each group, as participant numbers and time for recruitment were limited.

Exercise Buddies

Exercise buddies were professional carers who were currently working (or had previously worked) for MS Ireland in providing professional care for PwMS in their own homes (e.g. assistance with activities of daily living, dressing etc). All exercise buddies completed a training day conducted by the study researcher (ET) consisting of both practical and theoretical components. Objectives of the course for buddies were to understand the role and responsibilities in delivering the intervention, to gain knowledge and understanding of MS, to revise manual and therapeutic handling techniques, to re-familiarise with exercise equipment

and to review precautions when working with people with severe disabilities. Practical aspects included bed, wheelchair and standing frame transfers, passive movements, active, active assisted and passive joint range of motion and positioning. The importance of exercise was emphasised in addition to discussion of safety issues and aspects such as contractures or fatigue.

Interventions

The independent variables were the usual care and exercise buddy interventions, with the groups differing specifically in regards to dose of intervention and the individual delivering the intervention. After the baseline assessments had been completed, the primary care physiotherapist for each PwMS in the usual care group was asked to conduct visits consisting of routine care as frequently as they normally would over a 10 week period. The content and frequency of this was documented by the physiotherapists. Again following completion of the baseline assessments, an initial visit to the PwMS in the exercise buddy group was conducted by the primary care physiotherapist with the exercise buddy present. During this visit an individualised home exercise programme (HEP) was designed by the physiotherapist, which was then implemented by the exercise buddy for one hour per week for a 10 week period (exercise buddy worked unsupervised subsequent to physiotherapist approval). PwMS and exercise buddies were provided with contact details for the physiotherapists, and asked to make contact if adverse effects or safety issues were encountered. Physiotherapists were requested to document any adverse events and report to the research team to inform feasibility aspects.

Outcome assessment

Outcomes for participants and their caregivers were assessed at baseline and after the treatment phase (T2). Assessments were conducted by the study researcher (ET) who was blind to group allocation. The T2 assessments were taken within two weeks of the last week of the intervention, and prior to their assessment, participants were explicitly asked not to discuss their treatment over the 10 weeks during the assessment to maintain blinding.

The MSIS-29v 2 was chosen as the primary outcome measure and is a disease-specific health-related quality of life assessment tool that measures the impact of MS (Hobart et al., 2001). It has a physical and a psychological component and is transposed to a score out of 100, and higher scores reflect higher impact of MS. The scale has previously been found to be valid and reliable for use in PwMS, including in those with severe disabilities (Riazi et al., 2002, Riazi et al., 2003, McGuigan and Hutchinson, 2004, Gray et al., 2009). The Guy's Neurological Disability Rating Scale (GNDS) measures levels of disability across 12 categories including cognition, mood, speech, upper and lower limb function, and fatigue (Sharrack and Hughes, 1999). The GNDS is scored out of 60 and higher scores reflect higher disability levels. Its validity and reliability have been previously established in PwMS of varying disability levels, including those with severe MS (EDSS scores of up to 8.8) (Sharrack and Hughes, 1999, Rossier and Wade, 2002).

For carers, the outcome measure used was the Adult Carer Quality of Life (AC-QoL) questionnaire (Elwick et al., 2010). This measure was chosen as it had been extensively developed involving over 300 unpaid care-givers and aimed to address the potentially positive, as well as negative, aspects of caregiving to account for a wider range of the carer experience (Brouwer et al., 2008). Participant characteristics for both PwMS and their informal caregivers were collected at baseline. Data were also collected on recruitment and attrition rates to inform specific feasibility findings. The study researcher also documented

any informal feedback provided by stakeholders on the acceptability or implementation of intervention components or study outcome measures.

Statistical Analysis

Data were analysed using SPSS version 19. Data were assessed for normality using the Shapiro-Wilk test and examination of histograms and box plots. All data was found to be normally distributed. Differences in baseline scores between the groups were calculated by using independent t-tests. ANCOVA was used to adjust for pre-intervention scores and evaluate the difference between groups after treatment (T2). For ANCOVA the independent variable was the intervention and the dependent variable was the scores on the outcomes at T2. Given the preliminary nature of this evaluation, additional paired t-tests were used to evaluate the within-group difference between baseline and T2.

Results:

Recruitment across one region of MS Ireland and four HSE primary care physiotherapy sites over a three month period resulted in 29 participants. The flow of participants through the trial is detailed in figure 1. Fifteen PwMS were randomised to the exercise buddy group. The exercise buddy intervention was received by 12 participants in this group with three dropouts; a 13.8% attrition across the 12 week study period due to a combination of personal and logistical factors. For the informal caregivers, attrition was greater at 29.6% as 27 consented and were randomised, with data for 19 available for analysis.

‘insert figure 1 here’

Ten of the PwMS had one initial assessment session with a physiotherapist and exercise buddy. For two PwMS, a primary care physiotherapist supervised an additional session with the exercise buddy. Fourteen people were randomised to the usual care group. One participant withdrew from the study immediately due to being randomised to usual care. Of the remaining participants, eight received one session with a primary care physiotherapist. One participant had two visits from the physiotherapist, two had three visits and two participants had no contact with a physiotherapist.

Table 1 presents the data at baseline and the differences between groups for both PwMS and their informal caregivers. For PwMS, the exercise buddy group were significantly younger, but had not walked for an average of 4 years more. There were no significant differences in caregiver characteristics at baseline. Table 2 presents the outcome data at each time point for each group. ANCOVA was used to compare the two groups over the treatment phase. There was no violation of the assumptions of ANCOVA. After adjusting for pre-intervention scores there was no significant differences at T2 between groups on the MSIS-29 physical $F(1, 22)=0.754$, $p=0.395$, partial eta squared 0.033. For MSIS-29 psychological there was also no significant difference $F(1,22)=1.954$, $p=0.176$, $PES=0.082$. GNDS was also not significantly different $F(1,22)=1.944$, $p=0.177$ $PES=0.081$. Paired t-tests were used to investigate the change within each group between baseline and T2 (table 2). Only the exercise buddy group demonstrated significant improvements in MSIS physical and psychological domains.

For caregivers, after adjusting for pre-intervention scores there was no significant differences at T2 on the ACQOL $F(1, 16)=0.657$, $p=0.432$, partial eta squared 0.039. There were no significant differences in the ACQOL on any of the post hoc tests. Of particular note is that four of the caregivers refused to complete the ACQoL outcome measure at T2, reporting that

they did not like the use of the term “burden” within the questionnaire and that this did not reflect accurately their carer role with the person with MS.

‘insert table 1 here’

‘insert table 2 here’

Discussion:

The results of this pragmatic pilot study suggest that the exercise buddy model of care may be a feasible intervention with potentially positive effects for non-ambulatory people with MS on the physical and psychological impact of the disease.

Attrition rates of PwMS were less than previously observed rates in exercise trials for PwMS which ranged from 18% to 42% (Swank et al., 2013), and also less than the 20% proposed as a measure of trial quality (Schulz and Grimes, 2002, Fewtrell et al., 2008). Moreover, given the level of disability and complexity of everyday life for this population, this rate is not unexpected in a community setting. The higher rates of attrition seen in the carer group was hypothesised to be primarily due to the measure used. The use of the term “burden” in the ACQoL questionnaire caused several carers to refuse to complete the measure, therefore an alternative way of evaluating the effect on carers is required for future studies. Indeed, this finding echoes that of previous research within informal carers which found the term ‘burden’ may devalue the PwMS being cared for (Hughes et al., 2013). To account for this, future studies should consider using questionnaires such as the Caregiver Strain Index or a more generic alternative such as Assessment of Quality of Life (Khan et al., 2007).

Recruitment rates suggest that over a year, it would be possible to recruit 116 participants. The power calculation based on the observed change from baseline differences using 80% power shows that a sample size of 134 in each group (268 in total) would have 80% power to detect a difference in means of 5.11, assuming that the common standard deviation is 14.84 using a two group t-test with a 0.05 two-sided significance level. Therefore a recruitment period of over two years would be needed to recruit sufficient numbers for a fully powered study. Although this is unlikely to be feasible, it may be that randomised controlled trial (RCT) methods are not the best design to test this sort of pragmatic intervention. Although traditionally viewed as the 'gold standard' design, RCTs have come under increasing criticism for their lack of clinical utility and inability to reflect real-world effectiveness (Grapow et al., 2006, Hodgson et al., 2007). Therefore, further exploration of the exercise buddy model using a more 'pragmatic trial approach' may be of most benefit (Patsopoulos, 2011).

The analysis of these pilot study data suggests that there was no statistical difference between the interventions. The small number of participants and large variability in baseline and change scores may be responsible for this, as the within group analysis suggests significant improvements in both physical and psychological impact of MS following exercise buddy care for PwMS. The lack of significant difference between interventions might also be explained by the low "dose" of intervention which was one hour per week. The intervention combined a range of strategies including positioning and transfers so some carry over to other days was possible. While increasing the "dose" of intervention would be optimal, this pragmatic approach is more reflective of a potentially implementable and sustainable treatment, and is consistent with what is currently being provided in the community by MS Ireland using exercise buddies.

Using exercise buddies to augment the dose of physiotherapy received by this population is a pragmatic and potentially cost-effective intervention. There were no adverse events reported in this pilot study and a tendency for individual scores to increase was observed. The overwhelmingly positive physical and psychological benefits of this model have been highlighted in previous qualitative research (Toomey and Coote, 2013) and is supported by this preliminary data. Future exploratory research should further investigate this effect and include a thorough analysis of the costs of this model of augmented care and its benefits for both PwMS and their carers, utilising a more appropriate trial design. As previously highlighted, the cost of care for those with severe disability are significant (Kobelt et al., 2006), therefore ascertaining the potential cost benefits of the exercise buddy model would be of paramount importance for this population.

Limitations and difficulties experienced

The lack of impairment measures in this pilot study is a limitation, however the range and complex interaction between the impairments of these PwMS made it difficult to choose an impairment-based measure. We selected outcome measures that aimed to capture the impact of MS and disability levels of the PwMS that have been previously validated for this population. Nonetheless, measures such as the Goal Attainment Scale (Ottenbacher and Cusick, 1990) which can be personalised according to participant's main problems should be considered for use in future studies. Moreover, issues with the outcome measure used with caregivers were also experienced, as highlighted earlier in the discussion.

Another limitation to the pilot study was the variation in usual care received. The preliminary survey of primary care physiotherapists conducted prior to this study suggested that one visit

in 10 weeks was 'usual care'. However both the baseline data and that collected during the study suggests this is not the case. Whilst 85% of participants in the usual care group were seen by their primary care physiotherapist in the 10 weeks of the study, this care varied from one session to three sessions, while two participants received no intervention at all. This would suggest that future studies would need to document carefully the amount of treatment received in a control or usual care group. It also raises concerns regarding the dose of physiotherapy received in current practice. The lack of effect seen in the carer group may have also been attributable to the low dose of intervention, and that one hour per week may not have been enough to make a difference to them.

Conclusion:

This pilot study was a pragmatic evaluation of a model that is currently being used in community settings by MS Ireland and has shown excellent qualitative results. The intervention and outcome measures were feasible, however we suggest changing the carer outcome measure and adding a personalised measure of impairment for PwMS. Recruitment and retention rates suggest that although proceeding with a fully powered RCT would not be advisable, further exploratory work involving different study designs in addition to a cost analysis would be of use. A strength of this initial pilot study is a focus on both PwMS and their carers, an aspect that is often lacking in other studies. The study also adds to the limited existing evidence base on interventions for non-ambulatory PwMS. These data in conjunction with a previous qualitative exploration of the exercise buddy model of care suggest that further evaluation is warranted.

Conflict of interest:

The authors declare that there are no conflicts of interest to disclose.

Key points:

- Research into physiotherapy interventions for non-ambulatory people with Multiple Sclerosis (PwMS) and their carers is lacking
- ‘Exercise buddies’ are paid carers delivering a physiotherapy home exercise programme under the guidance of a physiotherapist and are currently in use by MS Ireland
- Qualitative research has shown positive physical and psychological benefits for PwMS and their carers but no quantitative assessments have been done to date
- This pilot study showed no between-group difference but some significant within-group improvements on impact of MS for exercise buddy group only
- The intervention and outcome measures were shown to be feasible, though some outcome measures should be altered
- Further exploratory work should consider an alternative study design to RCT and include a cost analysis

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Figure 1: Flowchart of participants through study

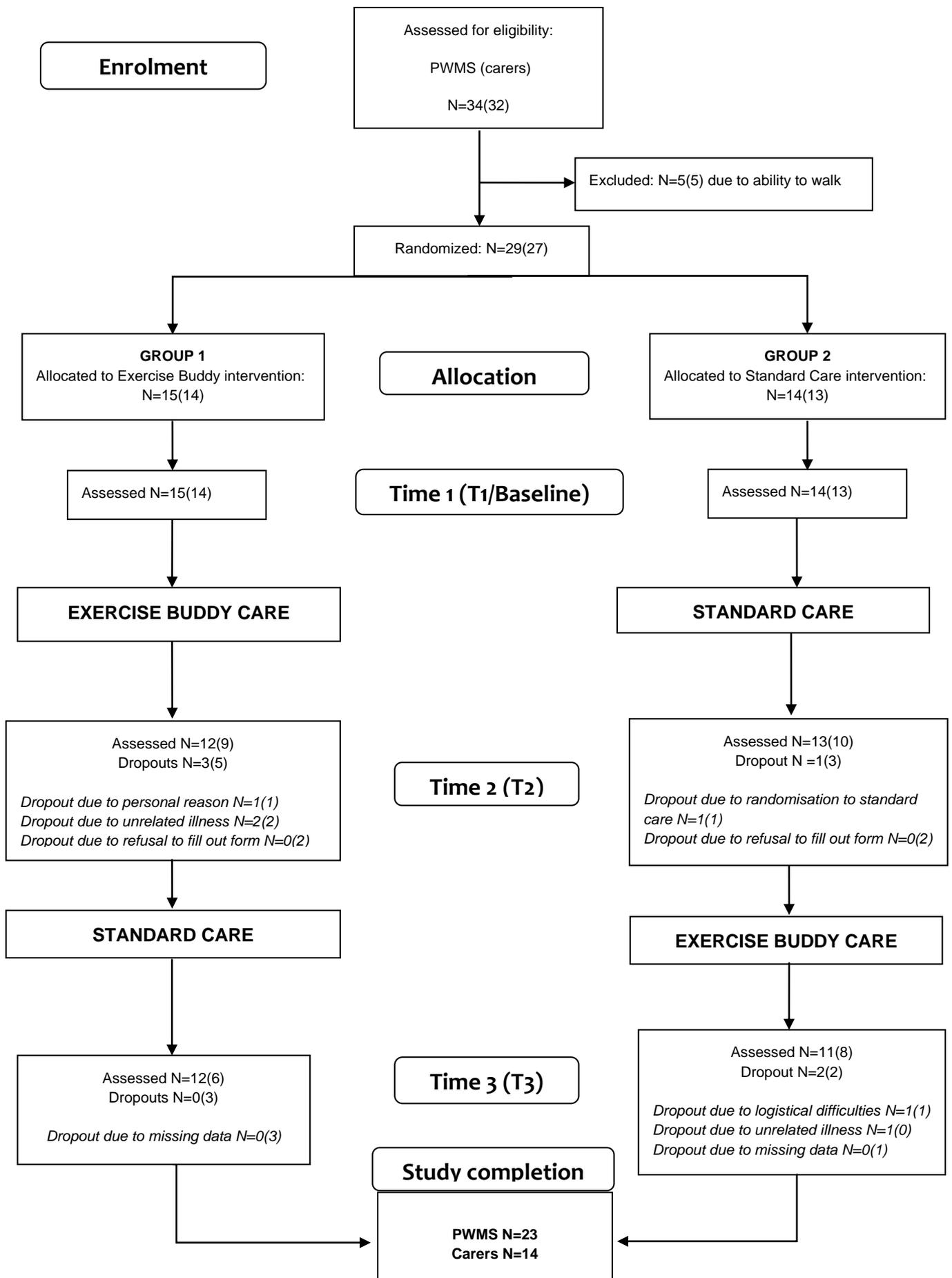


Table 1: Baseline Characteristics

Characteristic	Group 1	Group 2	P value
PWMS:			
Age (years (SD))	52.93 (8.3)	60.86 (9.5)	0.027 ^{†*}
Sex (frequency (%))			0.71 [‡]
Male	5 (33.3%)	6 (42.9%)	
Female	10 (66.7%)	8 (57.1%)	
Time since diagnosis (years (SD))	13.66 (7)	18.7 (14.9)	0.425 ^{††}
Time since last walked (years (SD))	8 (5.3)	4.45 (3.13)	0.039 ^{†*}
Self-reported regular (weekly) physical activity			0.215 [‡]
Yes	9 (60%)	12 (85.7%)	
No	6 (40%)	2 (14.3%)	
Current Treatment**			0.7 [‡]
Yes	6 (40%)	4 (28.6%)	
No	9 (60%)	10 (71.4%)	
Physiotherapy in last year			0.715 [‡]
Yes	9 (60%)	7 (50%)	
No	6 (40%)	7 (50%)	
MSIS Phys Score (mean (SD))	63.33 (24.77)	63.21 (16.07)	0.988 [†]
MSIS Psych Score (mean (SD))	40.99(29.81)	35.98 (27.92)	0.645 [†]
GNDS Score (mean (SD))	29.27 (6.43)	25.26 (6.47)	0.106 [†]
INFORMAL CAREGIVERS:			
Age (years, (SD))	51.13 (8.97)	48.62 (13.88)	0.568 [†]
Sex (frequency (%))			0.479 [‡]
Male	7 (46.7%)	5 (38.5%)	

Female	8 (53.3%)	8 (61.5%)	
Years caring for PwMS (SD)	9.32 (8.1)	13.5 (10.5)	0.263†
Own medical conditions			0.443‡
Yes	4 (26.6%)	2 (14.3%)	
No	11 (73.3%)	12 (85.7%)	
ACQoL Score (mean (SD))	64.33 (28.02)	81.08 (22.27)	0.095†
<p>‡ Mann-Whitney U test, † Independent samples t-test, ‡ Fisher's Exact test, PwMS – People with Multiple Sclerosis, SD – standard deviation, MSIS – Multiple Sclerosis Impact Scale, GNDS – Guy's Neurological Disability Scale, ACQoL – Adult Carer Quality of Life, *p value <0.05, significant, **Any physical intervention delivered by a professional, e.g. acupuncture/physiotherapy/massage</p>			

Table 2: Outcome scores at each timepoint				
	<i>T1</i>	<i>T2</i>	<i>Change between T1 and T2</i>	<i>P value for T1-T2</i>
PWMS :	<i>n=29</i>	<i>n=25</i>		
MSIS PHYS (mean (SD))				
Exercise Buddy	63.33 (24.77)	54.44 (24.28)	10.56 (14)	0.024*
Usual Care	63.21 (16.07)	59.29 (14.79)	5.45 (15.77)	0.237
MSIS PSYCH (mean (SD))				
Exercise Buddy	40.99(29.81)	34.26 (29.9328.66)	12.04 (13.13)	0.009*
Usual Care	35.98 (27.92)	36.47 (28.48)	0.00 (22.02)	1.00
GNDS (mean (SD))				
Exercise Buddy	29.27 (6.43)	27.06 (4.53)	1.03 (4.26)	0.421
Usual Care	25.26 (6.47)	22.95 (6.32)	2.26 (5.5)	0.165
INFORMAL CAREGIVERS:	<i>n=27</i>	<i>n=19</i>		
ACQoL (mean (SD))				
Exercise Buddy	64.33 (28.02)	68.2 (15.4)	-2.44 (12.2)	0.564
Usual Care	81.08 (22.27)	76.4 (16.69)	-0.30 (10.15)	0.928
*p value <0.05				